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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/357,423	07/20/1999	THOMAS M. BAER	17726-726	9233

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 01/14/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/357,423

Applicant(s)

BAER, THOMAS M.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 25-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 25-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicants' amendment filed on November 4, 2002 and entered as Paper No. 15. Claims 1-4 and 25-37 are pending.

Withdrawal of Rejections from Previous Office Action

- The rejection of claims 1 and 2 over Ek is withdrawn in view of Applicants' amendment to state that the reaction chamber is defined in part by the carrier and a portion of the carrier is included in the chamber.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4 and 25-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' have amended independent claims 1, 28 and 31 to recite that the reaction chamber is defined in part by the carrier and that a portion of the surface of the carrier is included in the reaction chamber. The specification does not provide support for such limitations. At page 16 of the specification, Applicants describe an extraction chamber, which serves as the reaction chamber. The extraction chamber is coupled to two capillaries. The chamber is defined in part by a spacer. The specification further states that the interior of the spacer defines the reaction chamber and that the spacer has a surface

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which can be mated with a sample carrier. This provides that the spacer defines the reaction chamber, not the sample carrier. Thus, there is no support for the sample carrier defining a portion of the reaction chamber and further, no support for the surface of the carrier being included in the reaction chamber. This is considered new matter and should be cancelled.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 2, 4, 26, 28, 29 and 31-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,084,660 to Shartle (hereinafter Shartle '660).

Shartle '660 discloses a device for measuring an analyte concentration of a blood sample. The device has a sample port (12), a channel (16), a measurement area (18), and a stop junction (22) (col. 5, lines 3-11). The sample port serves as a sample carrier and sample application area for introducing sample into the device. The sample port is also attached to layer 28, which provides a surface to which sample is applied. See figure 4. Channel (16) has a first end and a second end. The first end connects to the sample port. The second end connects to the measurement area (18). The channel provides a fluidic path between the sample port and measurement area. The measurement area provides a location for reagents to react with the sample and undergo changes providing an optical parameter for measuring the amount of analyte in the sample. The stop junction (22) provides a means for stopping flow of sample into the measurement area after it is filled. The device may be in the form of a laminate layered to form each of the chambers as shown in figure 2. In figures 7 and 8, Shartle '660 shows several

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different chambers having ports and conduits connected to each chamber and providing a fluid flow between the chambers.

Shartle '660 differs from the instant invention in that 1) the reference does not specifically disclose a reaction chamber and 2) there is no specific disclosure of a pump.

With respect to the reaction chamber, as recited in claims 1 and 4, Shartle '660 discloses that the measurement area contains a reagent (20) and that the sample undergoes a change when in contact with the reagent in the measurement area (col. 5, lines 14-21 and col. 6, lines 10-12) Therefore, it would have been obvious to one of ordinary skill in the art that the measurement area would serve as the reaction area also.

With respect to the pump as a part of the device, Shartle '660 discloses a bladder member (14). The bladder is compressed and creates a suction force to draw the sample into the device. It is the position of the Examiner that the bladder in Shartle '660 serves as a pump mechanism, absent evidence to the contrary.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the disclosure of Shartle '660.

5. Claims 3, 25, 27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shartle '660 as applied to claims 1, 4, 26, 28, 29 and 31-37 above, and further in view of US Patent 5,627,041 to Shartle (hereinafter Shartle '041).

Shartle '660 fails to disclose a dilution chamber in the device. Shartle '660 also fails to disclose the sample processing device as a centrifuge tube.

Shartle '041 discloses a laminated sample analyzing device similar to the device described in Shartle '660. The sample analyzing device contained several layers of material

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formed into chambers, reservoirs and channels. The device has a sample chamber, mixing chamber, reagent chamber, and dilution chamber. Shartle '041 teaches that the dilution chamber is necessary to dilute biological sample in order to accurately detect the amount of target analyte in a sample (col. 2, lines 11-20). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate a dilution chamber into the device of Shartle '660 to allow more accurate measurement of the analyte content in the sample.

Regarding the processing device being a centrifuge tube, Shartle '041 discloses incorporating the laminated analytical instrument into a centrifuge cartridge to allow fixed volume assays to move fluids throughout the device. It would have been obvious to one of ordinary skill in the art to incorporate the laminate structure of Shartle '660 into a centrifuge device to help move the sample around the device and allow the sample to contact the reagents and provide the user with a quantitative measurement of the concentration of analyte in the sample.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Shartle '660 and Shartle '041.

Response to Arguments

6. Applicant's arguments filed November 4, 2002 have been fully considered but they are not persuasive. Applicants' argue, with respect to the Shartle '660 and Shartle '041 references, that the references fails to teach or suggest a carrier mated with a processing device to form a reaction chamber defined in part by the carrier and wherein a portion of the surface of the carrier is disposed in the reaction chamber. Applicants provided to reasons for reaching this

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conclusion. The Examiner disagrees. The device of Shartle '660 has a sample port where sample is applied and flows by capillary action to channel (16). When the sample reaches channel (16), the channel serves as a sample carrier. The channel (16) is connected to the measurement zone (18). At this point, a reaction chamber exists, whereby the sample carrier is part of the reaction chamber. Thus, Shartle '660 provides a device wherein a portion of the sample carrier defines a reaction chamber with measurement zone (18). Here, the measurement zone is construed as the sample processing device.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC

January 10, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700